

App. No. 10/523,853  
Office Action Dated March 3, 2006

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**REMARKS**

Reconsideration is respectfully requested in view of the above amendments and following remarks. Claim 1 is amended. The limitation in claim 1 concerning the cationic surfactant being selected from the group consisting of benzyltrimethylammonium bromide, hexadecyltrimethylammonium bromide, lauryltrimethylammonium bromide, and zephiramine is supported for example by previous claim 5. The limitation in claim 1 concerning the acidic indicator being tetrabromophenol blue expressed by the Chemical Formula (1) is supported for example by previous claim 3. Claim 19 is a new independent claim and is supported for example by previous claims 1, 3, 6 and 7. Claim 20 is a new independent claim and is supported for example by previous claims 1, 3, 4, 5, 6, 7 and 8. Claim 21 is a new dependent claim and is supported for example by previous claim 9 and Example 6. Claim 21 is a new dependent claim and is supported for example by Example 7. Claims 2-18 have been canceled without prejudice or disclaimer. No new matter has been added. Claims 1 and 19-22 are pending.

***Claim rejections - 35 U.S.C. § 102/103***

Claims 1-4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau (US Patent No. 5,049,358). Claims 5, 7 and 9 are rejected under 35 U.S.C. 103(a) as being obvious over Lau in view of Iwata et al. (US Patent No. 5,565,363). Applicants respectfully traverse the rejections.

Claims 1, 19 and 20 are directed to a test piece containing a surfactant and a triphenylmethane-based acidic indicator. Claim 1 requires the surfactant to be cationic, selected from the group consisting of benzyltrimethylammonium bromide, hexadecyltrimethylammonium bromide, lauryltrimethylammonium bromide, and zephiramine. Claim 19 requires the surfactant to be nonionic, and in particular, polyethylene glycol. Claim 20 requires the combination of cationic and nonionic surfactants, limited to those respective surfactants as required by claims 1 and 19. Claims 1, 19 and 20 require the triphenylmethane-based acidic indicator to be tetrabromophenol blue (hereinafter, "TBPB"), expressed by Chemical Formula (1). If the test piece does not meet the composition requirements of claims 1, 19 and 20, the desired coloration sensitivity cannot be obtained. For example, as shown in Table 2, if the surfactant selected from the group listed above is not added to the TBPB, the coloration sensitivity of TBPB is not increased.

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The experimental work in the present specification supports the allowability of claims 1, 19 and 20. Briefly, test pieces were impregnated with urine having an albumin concentration of 0.3 mg/dL (negative) or 15 mg/dL (positive) (page 7, lines 21-24). Next, the impregnant was produced by adding a surfactant selected from the group listed above to the TBPB (Examples 1-7). The measurement results unexpectedly showed that the reflectance at an albumin concentration of 15 mg/dL was lower when the surfactant selected from the group listed above was added as compared to when no surfactant was added to the TBPB (page 10, lines 5-7). In fact, the differential  $\Delta$  (%) between the negative (0.3 mg/dL) and the positive (15 mg/dL) when the surfactant was added was about twice the  $\Delta$  of when no surfactant was added (page 8, lines 8-11). Thus, it is clear from the results that when the surfactant selected from the group listed above is added to the TBPB, higher sensitivity to albumin is obtained, thereby allowing proper detection of albumin even when the albumin concentration is low (about 10 to 20 mg/dL).

Lau does not disclose the surfactants required by claims 1, 19 and 20. Moreover, Lau discloses the use of a dual indicator reagent system with at least two kinds of indicators, rather than the single acidic indicator of the present claims. Therefore, there is no anticipation of the present claims by Lau.

In fact, Lau notes that optional ingredients, such as surfactants, that do not materially alter the nature and the function of the indicator dyes and/or the buffer and that do not interfere with the protein assay, also can be included in the dual indicator reagent composition (col. 14, lines 34-41). As such, the reference actually supports the position that the present findings for the surfactants required by claims 1, 19 and 20 are unexpected.

The rejection relies on Iwata for CTAB and polyethylene glycol as the surfactants in the test piece. The rejection's reliance on Iwata is misplaced. Iwata discloses the use of polyethylene glycol with bromothymol blue and thymol blue, which are indicators having a transition interval in the pH range higher than TBPB (Example 10 and Table 1; TBPB has a transition interval in the pH range lower than 5.5). As such, the reference fails to teach or suggest that polyethylene glycol would be an appropriate sensitizer for TBPB. Iwata also discloses in Table 1 that CTAB could be used with an acidic pH indicator having a transition interval in the pH range of 3.5 to 5.5 such as methyl red, but also notes that it is possible to use methyl red, etc. as the pH indicator if it is other than the triphenylmethane series (col. 4, lines 44-45). As such, it is not even clear from the reference whether CTAB would be an appropriate

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surfactant to use with triphenylmethane-based indicators at a pH range of 3.5 to 5.5, as CTAB is used only with bromothymol blue in the Examples.

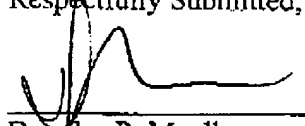
In view of the above, it is clear that the references fail to teach or suggest adding the surfactants required by claims 1, 19 and 20 to TBPB. Therefore, Applicants respectfully submit that claims 1, 19 and 20 and the dependent claims therefrom are patentable over Lau and Iwata, taken together or separately.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully Submitted,

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